HUMATIN- paromomycin sulfate capsule
Woodward Pharma Services LLC

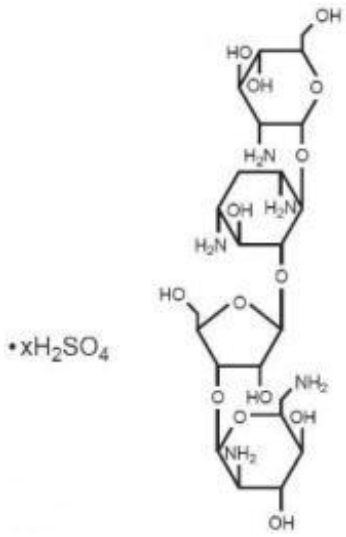
Rx Only

To reduce the development of drug-resistant bacteria and maintain the effectiveness of HUMATIN™ Capsules, and other antibacterial drugs, HUMATIN™ Capsules should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

DESCRIPTION

Paromomycin sulfate is a broad spectrum antibiotic produced by *Streptomyces riomosus* var. paromomycinus. It is a white, amorphous, stable, water-soluble product. Paromomycin sulfate is designated chemically as 0-2, 6-Diamino-2, 6-dideoxy-β -L-idopyranosyl-(1→3)-0-β -D-ribofuranosyl-(1→5)-0-[2-amino-2-deoxy-α -D-glucopyranosyl-(1→4)]-2-deoxystreptamine sulfate (salt). The molecular formula is $C_{23}H_{45}N_5O_{14}$•xH_2SO_4, with a molecular weight of 615.64 (base).

Its structural formula is:



Each capsule, for oral administration, contains paromomycin sulfate equivalent to 250 mg paromomycin. Each capsule also contains the following inactive ingredients: FD&C Blue # 1, D&C Red # 28, FD&C Red # 40, gelatin and titanium dioxide. The imprinting ink for the 250 mg capsule contains D&C yellow #10, FD&C blue # 1, FD&C blue # 2, FD&C red # 40, iron oxide black, pharmaceutical shellac glaze, and propylene glycol.

CLINICAL PHARMACOLOGY

The *in-vitro* and *in-vivo* antibacterial action of paromomycin closely parallels that of neomycin. It is poorly absorbed after oral administration, with almost 100% of the drug

recoverable in the stool.

INDICATIONS AND USAGE

Paromomycin sulfate is indicated for intestinal amebiasis–acute and chronic (NOTE-It is not effective in extraintestinal amebiasis); management of hepatic coma–as adjunctive therapy.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of HUMATIN™ Capsules and other antibacterial drugs, HUMATIN™ Capsules should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

CONTRAINDICATIONS

Paromomycin sulfate is contraindicated in individuals with a history of previous hypersensitivity reactions to it. It is also contraindicated in intestinal obstruction.

PRECAUTIONS

Prescribing HUMATIN™ Capsules in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

The use of this antibiotic, as with other antibiotics, may result in an overgrowth of nonsusceptible organisms, including fungi. Constant observation of the patient is essential. If new infections caused by nonsusceptible organisms appear during therapy, appropriate measures should be taken. The drug should be used with caution in individuals with ulcerative lesions of the bowel to avoid renal toxicity through inadvertent absorption.

Information for Patients

Patients should be counseled that antibacterial drugs including HUMATIN™ Capsules should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When HUMATIN™ Capsules is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by HUMATIN™ Capsules or other antibacterial drugs in the future.

PEDIATRIC USE

See DOSAGE AND ADMINISTRATION section.

ADVERSE REACTIONS

Nausea, abdominal cramps, and diarrhea have been reported in patients on doses over 3 g daily.

To report SUSPECTED ADVERSE REACTIONS, contact Woodward Pharma Services LLC at 844-200-7910 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION

Intestinal amebiasis: Adults and Pediatric Patients: Usual dose—25 to 35 mg/kg body weight daily, administered in three doses with meals, for five to ten days.

Management of hepatic coma:

Adults: Usual dose—4 g daily in divided doses, given at regular intervals for five to six days.

HOW SUPPLIED

HUMATIN™ Capsules each contain paromomycin sulfate equivalent to 250 mg paromomycin, are supplied as follows:

NDC 69784-510-01: Bottles of 100

The capsule is Dark Blue Opaque /White Opaque, imprinted with "HP 38" in black ink on the cap and on the body.

STORAGE

Store at 20°-25°C (68°-77°F) [See USP controlled Room Temperature] Protect from moisture.

Preserve in tight containers as defined in the USP.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

MANUFACTURED FOR:

Woodward Pharma Services LLC

Wixom, MI 48393

WOODWARD PHARMA

51UWW0000002US01

Revised: 11/2020

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 69784-510-01

Humatin™

Paromomycin Sulfate Capsules, USP

250 mg

100 Capsules

Rx only

HUMATIN

paromomycin sulfate capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:69784-510
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PAROMOMYCIN SULFATE (UNII: 845NU6GJPS) (PAROMOMYCIN - UNII:61JJC8N5ZK)	PAROMOMYCIN SULFATE	250 mg

Inactive Ingredients	
Ingredient Name	**Strength**

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
SHELLAC (UNII: 46N107B71O)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics

Color	WHITE (White opaque) , BLUE (Dark blue opaque)	**Score**	no score
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	HP;38
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69784-510-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/19/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA065173	02/19/2021	

Labeler - Woodward Pharma Services LLC (026749066)

Registrant - Heritage Pharmaceuticals Inc. d/b/a Avet Pharmaceuticals Inc. (780779901)

Establishment

Name	Address	ID/FEI	Business Operations
Heritage Pharma Labs Inc. d/b/a Avet Pharmaceuticals Labs Inc.		189630168	ANALYSIS(69784-510) , LABEL(69784-510) , MANUFACTURE(69784-510) , PACK(69784-510)

Revised: 2/2021 Woodward Pharma Services LLC